

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION**

LARRY COOPER,

*Plaintiff,*

v.

PFIZER, INC.,

*Defendant.*

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CIVIL ACTION H-14-3705

**ORDER**

Pending before the court is defendant Pfizer, Inc.’s (“Pfizer”) motion for judgment on the pleadings. Dkt. 12. After considering the motion, response, reply, and relevant law, the court is of the opinion that the motion should be GRANTED.

**I. BACKGROUND**

This is a product liability case in which plaintiff Larry Cooper alleges that he contracted diabetes and cataracts after taking Lipitor, a cholesterol-lowering drug manufactured and marketed by Pfizer. Dkt. 1-3 at 23-24. Cooper alleges negligence, negligent misrepresentation, negligent design, design defect, failure to warn, breach of express and implied warranties, fraud, constructive fraud, loss of consortium, and unjust enrichment. Dkts. 1-3, 1-4.

**II. LEGAL STANDARD**

Rule 12(c) allows a party to “move for judgment on the pleadings.” The same standards govern Rule 12(c) and Rule 12(b)(6) motions. *See Chauvin v. State Farm Fire & Cas. Co.*, 495 F.3d 232, 237 (5th Cir. 2007). In order to survive a motion to dismiss, the “complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550

U.S. 554, 570, 127 S. Ct. 1955 (2007)). “[T]he pleading standard Rule 8 announces does not require ‘detailed factual allegation,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Iqbal*, 556 U.S. at 667. “The court’s review is limited to the complaint, any documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint.” *Lone Star Fund V (U.S.), L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010).

### III. ANALYSIS

Cooper’s claims in this case are precluded by Texas Civil Practice and Remedies Code § 82.007, which establishes a rebuttable presumption that pharmaceutical companies are not liable in failure-to-warn cases where the Food and Drug Administration (“FDA”) approved the warnings accompanying the product. Section 82.007 provides, in relevant part:

(a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:

(1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act.

Tex. Civ. Prac. Rem. Code § 82.007. For the purposes of this section, a “products liability action” is:

any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories.

Tex. Civ. Prac. Rem. Code § 82.001(2).

Cooper concedes that Lipitor's warning was approved by the FDA and that § 82.007(a) applies. However, he tries to rebut the presumption created by § 82.007. Section 82.007(b) enumerates five ways a plaintiff can rebut the presumption set out in subsection (a):

(1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury;

(2) the pharmaceutical product was sold or prescribed in the United States by the defendant after the effective date of an order of the United States Food and Drug Administration to remove the product from the market or to withdraw its approval of the product;

(3)(A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration; (B) the product was used as recommended, promoted, or advertised; and (C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product;

(4)(A) the defendant prescribed the pharmaceutical product for an indication not approved by the United States Food and Drug Administration; (B) the product was used as prescribed; and (C) the claimant's injury was causally related to the prescribed use of the product; or

(5) the defendant, before or after pre-market approval or licensing of the product, engaged in conduct that would constitute a violation of 18 U.S.C. Section 201 and that conduct caused the warnings or instructions approved for the product by the United States Food and Drug Administration to be inadequate.

Tex. Civ. Prac. Rem. Code § 82.007(b). Cooper argues that he can rebut the presumption of non-liability because his claims meet the requirements of §§ 82.007(b)(1) and (b)(3).

#### **A. Fraud on the FDA**

Cooper cannot meet the requirements of §82.007(b)(1) which allows claims to move forward where the defendant has committed a fraud on the FDA. In order to rely on §82.007(b)(1), a plaintiff must show that the FDA itself has found fraud. *Lofton v. McNeil Consumer & Specialty Pharm.*,

672 F.3d 372 (5th Cir. 2012). Absent a finding of fraud by the FDA “§ 82.007(b)(1) is preempted.” *Id.* at 380. Cooper does not allege that the FDA has made a finding of fraud in this case. Rather, Cooper argues that § 82.007(b)(1) should not be preempted. Dkt. 14 at 10. This argument has been very clearly foreclosed by the Fifth Circuit’s ruling in *Lofton*. Accordingly, Cooper cannot rely on it here.

### **B. Off-Label Promotion**

Cooper also argues that he should be allowed to maintain his action based on § 82.007(b)(3), the off-label promotion exception. Cooper’s complaint alleges that he “was prescribed Lipitor for Off-Label usage, just as Defendant had marketed,” because “Plaintiff’s health care professionals did not find evidence that Plaintiff was at risk of three (3) cardiac risk factors,” and “Plaintiff only had hypertension and no prior cardiac risk factors.” Dkt. 1-3 at 19-20. These claims from Cooper’s complaint are directly contradicted by the medical records he attached as exhibits to his complaint as well as other allegations in his complaint. Specifically, Cooper alleges that he “was prescribed Lipitor for the treatment of his hypercholesterolemia and for coronary risk factors.” Dkt. 1-3 at 21. This is confirmed by the medical records attached to the complaint indicating that “the patient has been placed on low dose Lipitor at 10 mg each day for the treatment of his hypercholesterolemia.” Dkt. 1-5 at 54. Hypercholesterolemia was a labeled indication for Lipitor at the time it was prescribed. Dkt. 13-1.<sup>1</sup> Because Lipitor was prescribed to and used by Cooper for its intended and

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<sup>1</sup> The court takes judicial notice of the contents of the FDA approved label as allowed by Fed. R. Evid. 201 and *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (finding that judicial notice was appropriate for “publicly available documents and transcripts produced by the FDA, which were matters of public record and directly relevant to the issue at hand.”).

approved purpose, Cooper cannot use § 82.007(b)(3) to overcome the presumption of non-liability.<sup>2</sup>

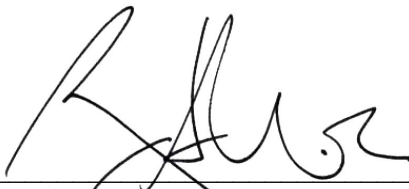
Because he cannot show the applicability of any exception to § 82.007(a), Cooper's claims based on Pfizer's alleged failure to warn of Lipitor's dangerous side effects must be dismissed. This includes all of his claims for fraud, negligence, strict liability, breach of warranty, loss of consortium, and unjust enrichment. *See* Tex. Civ. Prac. Rem. Code § 82.001(2).

#### IV. CONCLUSION

For the reasons outlined above, Pfizer's motion for judgment on the pleadings (Dkt. 12) is GRANTED. Plaintiff's claims are DISMISSED WITH PREJUDICE

It is so ORDERED.

Signed at Houston, Texas on May 13, 2015.

  
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Gray H. Miller  
United States District Judge

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<sup>2</sup> Cooper's response to Pfizer's motion alleges that he was prescribed Lipitor for hypercholesterolemia even though his physician never ordered laboratory testing to confirm the diagnosis. Dkt. 14 at 22. This is not enough to bring his claim under the any of the exceptions since he does not allege that it was prescribed or promoted for an off-label use.